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09/200,055 11/25/98 GARIBALDI

J 3176-7694

EXAMINER

QM22/0410

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ART UNIT

PAPER NUMBER

3763

DATE MAILED:

04/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/200,055

Applicant(s)

GARIBALDI ET AL.

Examiner

Michael M. Thompson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-40 have been considered but are moot in view of the new ground(s) of rejection. Upon reconsideration of the Anderson patent the Examiner has made a rejection on the merits. Please pay particular attention to the cited references of the instant application and their importance with respect to the claims.

Claim Rejections - 35 U.S.C. §102/103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 5-9, 11-26, and 28-40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Anderson ('362). Anderson ('362) teaches a medical device including a stylet or guide device maintaining a greater length than the tubular member and a magnetic means attached to the distal end of the stylet. It is the Examiners position that permeable and permanent magnets are inherently taught, to include other features such as a cylindrical magnetic tip, etc. The method is taught to utilize a second magnetic means

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for external placement over the orifice of the patient. The device is inherently pushed at the proximate end and pulled via magnetic force at the distal end. The magnetic material is inherently flexible with regard to other materials. The Examiner would also like to point out that when interpreting the pictures the stylet/guidewire shows metal as being the material of choice. (MPEP 608.02) It also refers to a spring, commonly made from metallic materials.

5. In the alternative, Anderson ('362) teaches the device as disclosed but does not get specific as to the "magnetic means" or the materials utilized. It is well settled in the art that one magnet may replace many magnets, or vice versa. It is also well settled in the art that "magnetic means" is interpreted as inherently disclosing both permeable or non-permeable substances so long as the material utilized displays magnetic properties. It is the Examiner's position that Anderson ('362) renders obvious if not inherent Applicant's invention and methods in light of the reasons mentioned above, and include all of the limitations herein. For the purpose of understanding the Examiner's position on magnets, the following is a basis for understanding magnets and their properties. It was suggested in 1907 that a ferromagnetic material be composed of a large number of small volumes called domains, each of which is magnetized to saturation. In 1931 the existence of such domains was first demonstrated by direct experiment. The ferromagnetic body, as a whole appears unmagnetized when the directions of the individual domain magnetizations are distributed at random. Each domain is separated from its neighbors by a domain wall. In the wall region, the direction of magnetization turns from that of one domain to that of its neighbor. The process of magnetization of magnetized materials, starting from a perfect unmagnetized state, comprises three stages: (1) Low magnetizing field. Reversible movements of the domain walls occur such that domains oriented in the general direction of the

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magnetizing field grow at the expense of those unfavorably oriented; the walls return to their original position on removal of the magnetizing field, and there is no remnant magnetization. (2)

Medium magnetizing field. Larger movements of domain walls occur, many of which are irreversible, and the volume of favorably oriented domains is much increased. On removal of the field, all the walls do not return to their original positions, and there is a remnant magnetization.

(3) High magnetizing field. Large movements of domain walls occur such that many are swept out of the specimen completely. The directions of magnetization in the remaining domains gradually rotate, as the field is increased, until the magnetization is everywhere parallel to the field and the material is magnetized to saturation. On removal of the field, domain walls reappear and the domain magnetizations may rotate away from the original field direction. The remnant magnetization has its maximum value. A permanent magnet can be visualized as the result of assembling the magnet from a large number of particles having a high value of saturation magnetization, each of which is a single domain, each having a uniaxial anisotropy in the desired direction, and each aligned with its magnetization parallel to all the others. Furthermore, with respect to permeable magnetic material, it is well known in the art that materials allowing

magnetic lines of force to pass through them are called nonpermeable, and materials that gather magnetic lines of force are said to be permeable. This is because metal acts as a magnetic shield because the force lines come from the pole of the magnet and do not pass through the metal material. Instead, they are gathered in, travel down the metal material, and re-enters the magnet at the other pole. Therefore, only magnetic materials are permeable. Furthermore, with respect to permeable magnetic material, it is well known in the art that materials allowing magnetic lines of force to pass through them are called nonpermeable, and materials that gather magnetic lines of

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force are said to be permeable. This is because metal acts as a magnetic shield because the force lines come from the pole of the magnet and do not pass through the metal material. Instead, they are gathered in, travel down the metal material, and re-enters the magnet at the other pole.

Therefore, only magnetic materials are permeable. Therefore it is further obvious to one of ordinary skill in the art at the time of invention to make such a design modification at the device level as the applicant has taught that such merely a design modification. Please note that since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art, claims to multiple magnets have been rejected supra.

6. Claims 4, 10, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson ('362). Anderson ('362) both teach the device substantially as claimed however fails to point out the "magnetic means" as more than one magnet, or multiple annular magnets radially spaced apart as specified. Anderson ('362) teaches such a magnet utilized in the same art. It is well settled that "magnetic means" incorporates any structure displaying magnetic field and forces. Anderson ('362) discloses the claimed invention except for explicitly stating that multiple magnets are along the device. It would have been obvious to one of ordinary skill in the art at the time of invention to make or use the device of Anderson with the multiple magnetic means disposed radially about the distal end of the catheter for the purposes of creating a region of increased angularity whether the magnet is whole or separate, since it has been held that mere duplication of the essential working parts of the device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,931,818. Although the conflicting claims are not identical, they are not patentably distinct from each other because they clearly teach a medical device including a stylet or guide device maintaining a greater length than the tubular member and a magnetic means attached to the distal end of the stylet and a method that teaches the utilization of a second magnetic means for external placement over the orifice of the patient. The device is inherently pushed at the proximate end and pulled via magnetic force at the distal end.

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Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please note these references in the event that amendments to the claims may institute combinations of references to meet the claims.

- a. Golden et al. (5,902,238 and 5622169) Both refer to a guide wire with an attached magnet extremely similar to applicant's device.
- b. Gabriel (5431640) refers to an apparatus that is directed through a external magnet.

Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

Any questions pertaining to informal matters such as the status of a case, missing portions of an Office Action, references, filing, paper matching, etc., should be directed to the Examiner's Legal Instruments Examiner (LIE), Rosalind Smith, at (703) 305-2440.

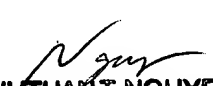
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, AnhTuan Nguyen, can be reached on (703) 308-2154. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520.

Michael M. Thompson

Patent Examiner

MT

April 5, 2001


ANHTUAN T. NGUYEN
PRIMARY EXAMINER

4/6/01